

**WEST VIRGINIA
SECRETARY OF STATE
JOE MANCHIN, III
ADMINISTRATIVE LAW DIVISION**

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Form #2

FILED
2004 JUL 28 P 3:43
OFFICE OF THE WEST VIRGINIA
SECRETARY OF STATE

NOTICE OF A COMMENT PERIOD ON A PROPOSED RULE

AGENCY: DHHR - Bureau for Public Health TITLE NUMBER: 64

RULE TYPE: Legislative CITE AUTHORITY: §§16-1-4 & 16-7-5

AMENDMENT TO AN EXISTING RULE: YES NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 34

TITLE OF RULE BEING AMENDED: Grade "A" Pasteurized Milk

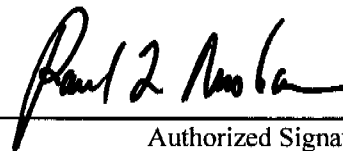
IF NO, SERIES NUMBER OF RULE BEING PROPOSED: _____

TITLE OF RULE BEING PROPOSED: _____

IN LIEU OF A PUBLIC HEARING, A COMMENT PERIOD HAS BEEN ESTABLISHED DURING WHICH ANY INTERESTED PERSON MAY SEND COMMENTS CONCERNING THESE PROPOSED RULES. THIS COMMENT PERIOD WILL END ON Aug. 27, 2004 AT 12:00 noon ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS:

Barb Taylor and Phil Jones
Office of Environmental Health Services
Bureau for Public Health
815 Quarrier Street, Suite 418
Charleston, WV 25301

THE ISSUES TO BE HEARD SHALL BE LIMITED TO THIS PROPOSED RULE.



Authorized Signature

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL

Brief Summary of the Rule

64 CSR 34 Grade "A" Pasteurized Milk

The proposed legislative rule will update the current Grade "A" milk rule which has been effective since July 1, 1980.

The proposed rule adopts by reference the majority of the federal model Grade "A" Pasteurized Milk Ordinance, 2001 Revision, published by the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, which establishes the sanitary standards for Grade "A" raw milk for pasteurization and Grade "A" pasteurized milk and milk products.

The use of the model ordinance facilitates the shipment and acceptance of milk and milk products of high sanitary quality in interstate and intrastate commerce.

Butter, cheese and ice cream are not Grade "A" milk products and their production is not affected by this rule except to the extent that processors prefer to use Grade "A" milk in the production of these products.

**Statement of Circumstances
Which Require the Proposed Rule**

**64 CSR 34
Grade "A" Pasteurized Milk**

The existing rule governing production of Grade "A" raw and pasteurized milk is outdated (based on the 1978 federal model ordinance) and no longer provides the necessary standards to protect the public from milkborne disease or to be considered equivalent to national standards for the purpose of interstate commerce.

The Public Health Service (PHS), Food and Drug Administration (FDA) recommended Grade "A" Pasteurized Milk Ordinance is the basic standard used in the voluntary "Cooperative State - PHS/FDA Program for the Certification of Interstate Milk Shipments," a program participated in by all fifty (50) States, the District of Columbia and U.S. Trust Territories. The National Conference on Interstate Milk Shipments has determined that states having rules based on federal model codes dated prior to 1991 are no longer substantially equivalent to the current Grade "A" Pasteurized Milk Ordinance, 2001 Revision.

The proposed rule adopts by reference the 2001 Revision of the federal model Grade "A" Pasteurized Milk Ordinance which would bring the State of West Virginia into conformity with national standards and up-to-date with technological advances in milk production and safety which have occurred since adoption of the previous rule in 1980.

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Grade "A" Pasteurized Milk 64CSR34

Type of Rule: **Legislative** **Interpretive** **Procedural**

Agency: WV Bureau for Public Health, Division of Health, Dept. of Health & Human Resources

Address: Building 3, Capitol Complex
Charleston, W. Va. 25305

1. Effect of the Proposed Rule	ANNUAL		FISCAL YEAR		
	Increase	Decrease	Current	Next	Thereafter
Estimated Total Cost	\$	\$	\$477,446.00	\$489,970.00	\$489,970.00
Personal Services			\$319,595.00	\$330,334.00	\$330,334.00
Current Expense			\$151,469.00	\$152,935.00	\$152,935.00
Repairs & Alterations					
Equipment			\$6,382.00	\$6,701.00	\$6,701.00
Other					
Revenue					

2. Explanation of above estimates.

Personal Services - The milk sanitation program is labor intensive, requiring numerous inspections of milk plants, dairy farms, single service bottle plants, milk tank trucks, truck wash stations; testing of milk processing equipment; raw and pasteurized milk sampling and testing; evaluation of milk hauling and sampling personnel; rating of raw milk supplies and milk plants for interstate shipment certification; and evaluation of milk laboratories. The WV Bureau for Public Health utilizes seven (7) state sanitarian, (5) laboratory technicians, and four (4) secretarial positions in whole or in part to conduct the state milk program. The positions are existing and no change in work force levels is anticipated.

Current Expense - Nearly 20% of current expense costs are devoted to travel and vehicle expenses necessary to conduct the in-field requirements of the milk sanitation program. The remainder of current expense costs are applied to office space rent, telecommunications, office supplies, laboratory supplies for running tests, and mailing costs.

Equipment - A number of test units are maintained for the milk sanitation program including:

	<u>Replacement Cost</u>
Charm SL, Snapshot and Parallax Antibiotic Test Units	\$11,411
Lumenite Pasteurizer Timing Test	\$ 4,443
Circulator/Heaters	\$ 4,500
Fossomatic 90 Somatic Cell Test	\$37,538
Fluorophos Phosphatase Test	\$ 6,240
Certified Test Thermometers	\$ 1,700

Yearly repair and replacement costs for the existing equipment were estimated at \$6,382 based on life expectancy. This would not cover the cost of replacement of individual units in the event of catastrophic loss.

3. Objectives of this rule: The Grade "A" Pasteurized Milk Rule is intended to insure a disease-free and drug residue-free pasteurized milk supply for all West Virginians. Milk continues to have the potential to serve as a carrier of disease and has at times been associated with disease outbreaks of major proportions. Animal drug residue in raw milk used for pasteurization continues to be a public health issue with over 200,000 pounds of antibiotic contaminated milk being dumped annually in West Virginia. This rule adopts by reference the 2001 Federal Model Grade "A" Pasteurized Milk Ordinance to replace the existing 25 year old state milk rule.

4. Explanation of Overall Economic Impact of Proposed Rule.

A. Economic Impact on State Government.

None. This rule revision will result in no additional economic impact on state government. The Grade "A" Pasteurized Milk program is an existing program with personnel and equipment already in place.

B. Economic Impact on Political Subdivisions; Specific Industries; Specific Groups of Citizens.

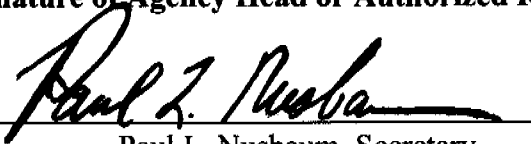
None. The U.S. Public Health Service, Food and Drug Administration Grade "A" Pasteurized Milk Ordinance (PMO) was developed with the assistance of milk sanitation and regulatory agencies at every level of federal, state, and local government, including both health and agriculture departments; all segments of the dairy industry, including producers, plant operators, equipment manufacturers, and associations; many educational and research institutions; and with comments from many individual sanitarians and others. The Grade "A" PMO is the basic standard used in the voluntary cooperative State - U.S. Public Health Service program for the certification of Interstate Milk Shippers (IMS), a program participated in by all 50 states, the District of Columbia, and U.S. Trust Territories. Milk not produced under the IMS program is not permitted to be sold in interstate commerce.

C. Economic Impact on Citizens/Public at Large.

None. West Virginia citizens and the public at large are assured of a safe, wholesome milk supply. Safety from diseases which can be carried by milk eliminates citizen medical expenses which would otherwise be associated with drinking milk. Reducing or eliminating animal drug residue in the milk supply reduces the development of antibiotic resistant strains of bacteria, assuring that existing antibiotics remain effective in treating disease.

Date: 7/28/04

Signature of Agency Head or Authorized Representative:


Paul L. Nusbaum, Secretary
Department of Health and Human Resources

**TITLE 64
LEGISLATIVE RULES
BUREAU FOR PUBLIC HEALTH
DEPARTMENT OF HEALTH AND HUMAN RESOURCES**

**SERIES 34
GRADE "A" PASTEURIZED MILK**

FILED

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SECRETARY OF STATE
WEST VIRGINIA

§64-34-1. General.

1.1 Scope. -- This legislative rule establishes the minimum requirements for the production, transportation, processing, handling, sampling, examination, labeling, and sale of Grade "A" milk and milk products, imitation milk and imitation milk products, and non-dairy products; the inspection of dairy farms, milk plants, receiving stations, transfer stations, milk tank truck cleaning facilities, milk tank trucks and bulk milk haulers/samplers; the issuing, suspension, and revocation of permits to milk producers, bulk milk haulers/samplers, milk tank trucks, milk transportation companies, milk plants, receiving stations, transfer stations, milk tank truck cleaning facilities, haulers, and distributors, and the fixing of penalties.

1.2. Authority. -- WV Code §§ 16-1-4 and 16-7-5.

1.3. Filing Date. --

1.4. Effective Date. --

1.5. Repeal and Replacement of Former Rules. -- This legislative rule repeals and replaces Division of Health rule, "Grade 'A' Pasteurized Milk," 64CSR34, filed February 1, 1980, and effective July 1, 1980.

1.6. Applicability. -- This rule applies to every person, as defined in this rule, who in any manner establishes, conducts, controls, manages, maintains, owns, or operates a facility included under the scope of this rule.

1.7. Enforcement. -- This rule is enforced by the Commissioner of the Bureau for Public Health.

§64-34-2. Incorporation By Reference of Federal Model Grade "A" Pasteurized Milk Ordinance.

2.1. The following portions of the Grade "A" Pasteurized Milk Ordinance, 2001 Revision, as published by the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, including administrative procedures, public health reasons, tables and

illustrations, are hereby incorporated by reference:

2.1.a. Section 1, Definitions;

2.1.a.1. Except that definition "BB. Regulatory Agency" means the Commissioner, Bureau for Public Health, West Virginia Department of Health and Human Resources, or his or her designee. The term "regulatory agency" also means the appropriate agency having jurisdiction and control over matters embraced within these milk rules.

2.1.a.2. The following definitions shall be added to Section 1:

2.1.a.2.A. "EE. Imitation Milk and Imitation Milk Products and Non-Dairy Products -- Products manufactured from vegetable fats (oils) or other derivatives other than milk fat and milk solids."

2.1.a.2.B. "FF. Adulterated Milk and Milk Products -- Any milk or milk product is deemed to be adulterated (1) if it bears or contains any poisonous or deleterious substance in a quantity which may render it injurious to health; (2) if it bears or contains any added poisonous or deleterious substance for which no safe tolerance has been established by State or Federal rules, or in excess of such tolerances, if one has been established; (3) if it consists, in whole or in part, of any substance unfit for human consumption; (4) if it has been produced, processed, prepared, packaged, or held under insanitary conditions; (5) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (6) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is."

2.1.a.2.C. "GG. Misbranded Milk and Milk Products -- Milk and milk products are misbranded (1) when their container or containers bear or accompany any false or misleading written printed or graphic matter; (2) when they do not conform to their definitions as contained in this rule; and (3) when they are not labeled in accordance with this rule."

2.1.a.3. The following statement is added to Definition P, Milk Products: "This definition shall include cottage cheese and dry curd cottage cheese and such other products as may be designated as a milk product by the Regulatory Agency."

2.1.b. Section 2, Adulterated or Misbranded Milk or Milk Products;

2.1.b.1. Footnote 1 referenced in Section 2 means the State of West Virginia.

2.1.c. Section 3, Permits;

2.1.c.1. Footnote 1 referenced in Section 3 means the State of West Virginia.

2.1.d. Section 4, Labeling;

2.1.e. Section 5, Inspection of Dairy Farms and Milk Plants;

2.1.f. Section 6, The Examination of Milk and Milk Products;

2.1.f.1. The following is added to Section 6, The Examination of Milk and Milk Products number 4: "When multiple samples of the same milk or milk products or imitation milk or imitation milk products or non-dairy products, except for aseptically processed products, are collected from the same producer or processor from multiple tanks or silos on the same day, the laboratory results are averaged arithmetically by the Regulatory Agency and recorded as the official results for that day. This is applicable for bacterial (standard plate count and coliform), somatic cell count and temperature determinations only."

2.1.g. Section 7, Standards for Grade "A" Milk and Milk Products;

2.1.g.1. The following is added to Standards for Grade "A" Pasteurized, Ultra-Pasteurized and Aseptically Processed Milk and Milk Products, Item 5p, Separate Rooms, Administrative Procedures: "7. Cottage cheese vats shall be located in a separate room, maintained free from insects and other vermin, and kept in a clean condition. Provided, that in facilities existing prior to the effective date of this rule, cottage cheese vats may be located in the processing room when there is no evidence of overcrowding, excessive traffic, condensation or splash and cottage cheese vats located in such processing rooms shall be equipped with multi-service or single-service covers which shall be kept in place at all times during the setting operation."

2.1.g.2. The following is added to Standards for Grade "A" Pasteurized, Ultra-Pasteurized and Aseptically Processed Milk and Milk Products, Item 7p, Water Supply, Administrative Procedures: "9. Water supply outlets are provided immediately available to the cottage cheese vats. The hose for transport of water, for washing cottage cheese curd, shall be arranged in such a way as to preclude the possibility of the hose touching the floor or the product."

2.1.g.3. The following is added to Standards for Grade "A" Pasteurized, Ultra-Pasteurized and Aseptically Processed Milk and Milk Products, Item 10p, Sanitary Piping: "Provided, that cottage cheese, cheese dressings or cheese ingredients may be transported by other methods which protect the product from contamination."

2.1.g.4. The following is added to Standards for Grade "A" Pasteurized, Ultra-Pasteurized and Aseptically Processed Milk and Milk Products, Item 18p, Bottling and

Packaging: "Provided, that cottage cheese, dry curd cottage cheese and reduced fat or lowfat cottage cheese may be transported in sealed containers in a protected, sanitary manner from one plant to another for creaming and/or packaging. If suitable equipment is not available for packaging dry curd cottage cheese, other methods of packaging which eliminate possible chances of contamination may be approved by the Regulatory Agency."

2.1.g.5. The following is added to Standards for Grade "A" Pasteurized, Ultra-Pasteurized and Aseptically Processed Milk and Milk Products, Item 18p, Bottling and Packaging, Administrative Procedures: "13. If cottage cheese, and dry curd cottage cheese are protected in a sanitary manner, they may be transported in sealed containers from one plant to another for creaming and/or packaging."

2.1.g.6. The following is added to Standards for Grade "A" Pasteurized, Ultra-Pasteurized and Aseptically Processed Milk and Milk Products, Item 19p, Capping, Administrative Procedures, 1: "Provided further, that if suitable equipment is not available for capping cottage cheese, dry curd cottage cheese and reduced fat or lowfat cottage cheese, other methods of capping which eliminate possible chances of contamination may be approved by the Regulatory Agency."

2.1.g.7. The following is added to Standards for Grade "A" Pasteurized, Ultra-Pasteurized and Aseptically Processed Milk and Milk Products, Item 19p, Capping, Administrative Procedures, 4: "Closures for cottage cheese, dry curd cottage cheese and reduced fat or lowfat cottage cheese containers shall extend over the top edges of the container so as to protect the product from contamination during subsequent handling."

2.1.g.8. The following is added to Standards for Grade "A" Pasteurized, Ultra-Pasteurized and Aseptically Processed Milk and Milk Products, Item 19p, Capping, Administrative Procedures: "5. Provided, that this requirement shall not apply to cottage cheese, dry curd cottage cheese and reduced fat or lowfat cottage cheese container closures, when such closures are supplied in a totally enclosed package, or wrapped so as to protect the closures."

2.1.h. Section 8, Animal Health;

2.1.i. Section 9, Milk and Milk Products Which May Be Sold, except that the words "In the State of West Virginia" are substituted for the words "From and after twelve (12) months from the date on which this Ordinance is adopted;"

2.1.i.1. The following is added to Section 9, Milk and Milk Products Which May Be Sold: "The practice of selling shares or other interests in dairy animals as a means of providing unpasteurized milk to the final consumer is prohibited."

2.1.j. Section 10, Transferring; Delivery Containers; Cooling;

2.1.k. Section 11, Milk and Milk Products From Points Beyond the Limits of Routine Inspection, except under Administrative Procedures number 7 the words "This provision will expire on December 31, 2003 unless extended by future Conference action;" are deleted;

2.1.l. Section 12, Plans for Construction and Re-Construction;

2.1.m. Section 13, Personnel Health;

2.1.n. Section 14, Procedure When Infection or High Risk of Infection Is Discovered;

2.1.o. Appendix A, Animal Disease Control;

2.1.p. Appendix B, Milk Sampling, Hauling and Transportation;

2.1.q. Appendix C, Dairy Farm Construction Standards and Milk Production;

2.1.r. Appendix D, Standards for Water Sources;

2.1.s. Appendix E, Examples of 3-Out-of-5 Compliance Enforcement Procedures;

2.1.t. Appendix F, Sanitization;

2.1.u. Appendix G, Chemical and Bacteriological Tests;

2.1.v. Appendix H, Pasteurization Equipment and Procedures;

2.1.w. Appendix I, Pasteurization Equipment and Controls-Tests;

2.1.x. Appendix J, Standards for the Fabrication of Single-Service Containers and Closures for Milk and Milk Products;

2.1.y. Appendix L, Applicable Regulations, Standards of Identity for Milk and Milk Products and the *Federal Food, Drug, and Cosmetic Act*;

2.1.z. Appendix N, Drug Residue Testing and Farm Surveillance; and

2.1.aa. Appendix O, Vitamin Fortification of Fluid Milk Products.

2.2. The Federal Model Grade "A" Pasteurized Milk Ordinance is available on the internet at: <http://www.cfsan.fda.gov/~ear/pmo01toc.html>.

§64-34-3. Imitation Milk and Imitation Milk Products and Non-Dairy Products.

3.1. All plants processing imitation milk, imitation milk products or non-dairy products in West Virginia shall comply with the applicable requirements of Section 2.1.g, 2.1.j, 2.1.m, and 2.1.n of this rule.

3.2. All products and ingredients used in the manufacture of imitation milk, imitation milk products or non-dairy products shall be clean, safe and wholesome. Finished products shall meet the bacteriological standards established herein for pasteurized milk and milk products.

3.3. Imitation milk, imitation milk products and non-dairy products shall be processed after the completion of the day's processing and bottling or packaging of all Grade "A" milk or milk products. Should operational practices require that such products be processed during other periods, all food contact equipment and piping common to the products shall be disassembled, cleaned and sanitized or cleaned and sanitized by an approved clean-in-place system before processing or allowing Grade "A" milk or milk products to come in contact with equipment or piping.

§64-34-4. Clarification of Interstate Responsibilities.

4.1. The Commissioner may enter into written or verbal agreements with the Regulatory Agency of states neighboring West Virginia for the purpose of clarifying regulatory responsibilities when a facility falling under the scope of this rule operates concurrently in West Virginia and the neighboring state.

§64-34-5. Penalty for Violating Provisions of Rule.

5.1. Any person violating any of the provisions of this rule, or orders issued pursuant to this rule, is punishable by a fine of not less than fifty dollars (\$50.00) nor more than five hundred dollars (\$500.00) as provided under WV Code §16-1-18.

§64-34-6. Administrative Due Process.

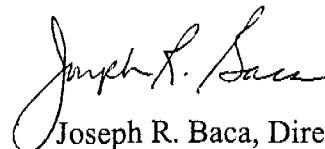
6.1. Any person adversely affected by the enforcement of this rule desiring a contested case hearing to determine any rights, duties, interests, or privileges shall do so in accordance with the Bureau for Public Health rule, "Rules and Procedures for Contested Case Hearings and Declaratory Rulings," 64CSR1.

Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835
(301) 436-1600

CERTIFICATION OF TRUE COPY

Pursuant to the provisions of Rule 44 of the Federal Rules of Civil Procedure, I hereby certify that the copy attached of the *Grade "A" Pasteurized Milk Ordinance, 2001 Revision*, is a true copy of material on file in the Food and Drug Administration, Department of Health and Human Services and is a part of the official records of said Administration and Department.

In witness whereof, I have pursuant to the provisions of Title 42, United States Code, Section 305, and 21 CFR 5.22, hereto set my hand and cause the seal of the Department of Health and Human Services to be affixed this 4th day of April, 2003.



Joseph R. Baca, Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

By direction of the Secretary
of Health and Human Services

